

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: Q. S. DEGHAN; Art Unit: 1791; Docket No.: 2701

In RE: Application of Reiner BARTSCH

Ser. No.: 10/625,582

Filing Date: July 23, 2003

**Title: METHOD FOR PREVENTING CONTAMINATION OF AN
INNER SURFACE OF A HOLLOW GLASS BODY BY
ALKALI COMPOUNDS AND GLASS CONTAINER,
ESPECIALLY FOR MEDICINAL PURPOSES**

July 24, 2009

**REPLY TO THE EXAMINER'S ANSWERTO THE
ARGUMENTATION IN THE APPEAL BRIEF**

Hon. Commissioner of Patents
and Trademarks,
Washington, D.C. 20231

Sir:

In response to the Examiner's Answer mailed on April 27, 2009 to the
argumentation in the Appeal Brief, please consider the following reply to the
Examiner's Answer in accordance with M.P.E.P. 1208:

I. STATUS OF THE CLAIMS

1. Method claims 1 to 10 were canceled.
2. Glass container claims 11 to 16 were withdrawn from consideration, but have not been canceled.
3. Method claims 17 to 31 have been canceled.
4. Claims 32 to 46 have been rejected on various grounds and are the claims on appeal, i.e. the rejections of claims 32 to 46 are being appealed.
5. The rejection of claims 32 to 46 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, was withdrawn by the Examiner's Answer of April 27, 2009.
6. Claims 32 to 39 and 41 to 46 stand rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.
7. Claims 32 to 35 and 40 to 41 stand rejected as unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Bennett, et al (US 3,985,535).
8. Claims 36 to 39 and 42 stand rejected as unpatentable under 35 U.S.C. 103

(a) over Ritt, et al (US 4,516,998), in view of Bennett, et al (US 3,985,535), and Schul (US 4,010,022).

9. Claims 43 and 44 stand rejected as unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Ott, et al (US Published Patent Application 2004/0176237).

10. Claims 45 and 46 stand rejected as unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Ott, et al (US Published Patent Application 2004/0176237) and Schul (US 4,010,022).

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(1) Whether claims 32 to 39 and 41 to 46 fail to particularly point out and distinctly claim the subject matter of the invention as required by 35 U.S.C. 112, second paragraph.

(2) Whether claims 32 to 35 and 40 to 41 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Bennett, et al (US 3,985,535).

(3) Whether claims 36 to 39 and 42 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Bennett, et al (US 3,985,535), and Schul (US 4,010,022).

(4) Whether claims 43 and 44 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Ott, et al (US Published Patent Application 2004/0176237).

(5) Whether claims 45 and 46 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al (US 4,516,998), in view of Ott, et al (US Published Patent Application 2004/0176237) and Schul (US 4,010,022).

III. ARGUMENTATION

1. REJECTION OF CLAIMS 32 to 46 UNDER 35 U.S.C. 112, 2nd ¶

In section (10) of the Examiner's answer the reasons for maintaining the rejection of independent claims 32, 36, 42, 43, 45 and dependent claim 41 under 35 U.S.C. 112, 2nd ¶, for omitting an essential step are presented. The Examiner's answer responds to section B of the argumentation presented in appellants' appeal brief. According to the Examiner's answer it is not clear how a bottom of the glass tube can be opened when it does not appear to have been closed in the first place.

In this connection the relevant steps of the aforesaid method claims are: b) or c): thermally cutting the hollow glass tube that is clamped in a vertical orientation, thereby forming a tube piece for discard and a bottom of the hollow glass tube clamped in the vertical orientation, and c) or d): thermally opening the bottom of the hollow glass tube by heating the bottom.

In formulating this indefiniteness rejection the feature b) in claims 32, 36, 42 and feature c) in claims 43 and 45, respectively, of thermally cutting include "forming [...] a bottom of said hollow glass tube clamped in said vertical orientation" has been ignored. This feature clearly requires that the hollow glass tube always produces "a bottom" after the lower tube piece is cutoff of the main

tube. Therefore, there is no lack of nexus or connection between forming "a bottom" and providing the hollow glass tube clamped in the vertical position.

Appellants respectfully disagree with the Examiner's answer with respect to the scope of the term "open". The meaning of the term "open" includes "expand" or "widen" and is not limited to opening an article in a completely closed state. For example, consider the following sentence: The wound or gash in the skin of the man opened under the strain. This sentence means that the wound or gash expanded or widened under the applied strain and is a perfectly valid meaning of the term "open".

Although there is no explicit definition of the term "open" in the appellants' specification, this latter meaning is fully consistent with the disclosure in the Detailed Description and is supported by the context of appellants' specification.

Furthermore the Examiner's answer is somewhat contradictory regarding the meaning of "open". In the middle of the first paragraph on page 12 it is alleged that the bottom is not closed at all, whether partially or completely, while at the end of the same paragraph it is stated that in light of the prior art used in the rejections, it will be assumed that the bottom formed by thermally cutting is closed when the thermally cutting is preformed.

Furthermore one of ordinary skill in the glass arts would recognize that it is not important whether the bottom is partial or completely closed when the tube piece for discard is thermally cut away from the hollow glass tube. One skilled in the art knows that the melting glass of the bottom will constrict in one way or

another. In practice this happens to some extent so that the bottom must be widened or opened in the next step. This is the important information and nothing else than what is literally covered by the current claim wording. Furthermore the claim wording encompasses both the widening of an existing opening or the opening of a completely closed bottom.

It is well established that breadth is **not** equivalent to indefiniteness or vagueness according to M.P.E.P. 2173.04.

Independent claims 32, 36, 42, 43, 45 and dependent claim 41 claim broadly as far as the "opening of the bottom" is concerned but the two covered situations are not indefinite: either the bottom formed by the thermally cutting is completely closed and subsequently opened or it is partially closed and opened further.

For the reasons presented in the appeal brief and the aforesaid additional reasons Honorable Board of Patent Appeals and Interferences is respectfully requested to overturn the rejection of claims 32 to 39 and 41 to 46 under 35 U.S.C. 112, second paragraph, for indefiniteness.

2. THE REJECTION OF CLAIMS 32 TO 35 AND 40 TO 41 AS OBVIOUS OVER RITT IN VIEW OF BENNET

The Examiner's answer states that evidence that Ritt does not produce an overpressure during thermal processing has not been presented in the appeal brief. Appellants respectfully disagree with the position of Office in this regard because the thermal processing of e.g. appellants' claim 32 includes the

thermally cutting to length and the thermally opening steps. Thus according to e.g. step d) of claim 32 the overpressure is provided during the thermally cutting to length and the thermally opening steps. Ritt does not provide the overpressure during these critical steps during which alkali release occurs when the tube with the closed ends, which is the starting point of their method, is made.

Appellants do provide evidence of the aforesaid situation on pages 24 to 26 in section C of the argumentation section of the appeal brief in the form of quotations from the M.P.E.P. 2143.03 and citations of locations of critical disclosure in the US Patent of Ritt. The method claimed by Ritt as noted on page 25 of the appeal brief does start with a glass tube that is closed at both ends. Appellants are concerned with the formation of this sort of glass tube and the closing of the ends of the tube because those steps can produce the alkali deposits that the appellants' claimed method avoids and are unacceptable in certain applications. See the last paragraph on page 25 of the appeal brief for the explanation of the reasons that the tube of Ritt would contain the alkali deposits.

The Examiner's answer contends that the dot-shaped opening at one of the closed ends of the tube according to Ritt is equivalent to the stopper claimed in claims 32 to 35 and 40 to 41. Particularly, the Examiner's answer continues by stating that the dot-shaped opening produces the same effect of creating an overpressure in the tube and it is therefore obvious to one of ordinary skill in the art to substitute a closed end having a hole with a stopper having an opening.

Appellants respectfully disagree for the following several reasons. The argument on page 25, last paragraph, of the appeal brief was not given weight.

The production of the intermediate product according to Ritt, namely closing the glass tube at both ends and forming a dot-shaped opening on one end with a jet flame counteracts the effect that is going to be achieved according to the invention, namely, to avoid a deposition of alkali on the interior surface of the glass products. It is obvious that the problem underlying the invention is made even worse when the process according to Ritt is performed. In that light it seems to be not enough to simply state that creating an overpressure can be achieved in both ways.

Moreover, "thermal processing" according to the claims at issue expressly includes "thermally cutting to length" and "thermally opening the bottom" (e.g. see the last part of the steps d of claims 32 and 36). In contrast, Ritt does not disclose or suggest the step of thermally opening the bottom that results from thermally cutting the hollow glass tube clamped in the vertical orientation as claimed in e.g. step c of claim 32. According to Ritt ampoules are produced from a glass tube with an open upper end, particularly, with the dot-shaped opening (initially sealed by a film) at the top. The ampoules are then produced by heating a portion of the circumference of the tube spaced at a distance from the lower end of the tube corresponding to the length of the ampoule to be produced in order to soften the sides of the tube. The softened sides are formed into a neck shape for the ampoule whereby overpressure develops in the tube and the sealed dot-shaped opening at the top of the tube bursts open. Still, the tube is not opened at the lower end. Thus, the alkali, if present, will rise to the top of the ampoule, while the gas escapes through the small dot-shaped opening but will

still be deposited on the inner surface of the tube. Finally, the ampoule is melted off from the remaining upper tube portion whereby two closed ends are formed, one at the top of the cut-off ampoule and another at the bottom end of the remaining glass tube. Thus, the tube is closed again at its lower end without having been opened during entire process.

It is further noted that the lower bottom of the tube becomes the bottom of the next ampoule while according to the invention the lower bottom of the tube will be thermally opened in order to form the opening of the next ampoule. In other words, the ampoule is manufactured in a reversed configuration.

Thus one skilled in the glass arts would not use the process according to Ritt to produce glass tubes if the problem regarding alkali deposition was considered to be important. To be sure in the case of many applications it is not an important problem, but in the case of containers for pharmaceutical products it can be a significant problem. The reduction of such alkali deposits in glass containers containing pharmaceutical products is an issue of considerable importance to the public and the production of containers that avoid such depositions should be encouraged.

For the reasons presented in the appeal brief and the aforesaid additional reasons Honorable Board of Patent Appeals and Interferences is respectfully requested to overturn the rejection of claims 32 to 35 and 40 to 41 as unpatentable under 35 U.S.C. 103 (a) over Ritt, et al, in view of Bennett, et al.

3. THE REJECTION OF CLAIMS 36 TO 39 AND 42 AS OBVIOUS OVER RITT IN VIEW OF BENNET AND SCHUL

The Examiner's answer only briefly addresses the arguments to overturn the rejection of claims 36 to 39 and 42 as unpatentable under 35 U.S.C. 103 (a) over Ritt in view of Bennett and Schul. These arguments were presented in second D of the argumentation section of the appellants' appeal brief. It is respectfully submitted that the disclosures in the prior art of record have been misinterpreted in formulating this rejection.

The inventive methods of Ritt do not include thermal opening of the bottom of the glass tube as alleged in the reasons for this rejection of claims. The final Office Action under item 12 on page 7 states that Ritt discloses "heating the lower end of the hollow glass tube to thermally open the bottom" in paragraph 12 on page 7. This is not part of the inventive method of Ritt because the disclosure in column 1, lines 10 to 52, only refers to state of the art vial production. Deviating from this standard prior art technique described in the introduction of Ritt, Ritt teaches a method of ampoule production starting with a glass tube having a permanently closed bottom. His production method for vials provides for vertically mounting the glass tube having the dot-shaped hole at the bottom end and being closed at the top which is also teaching that is opposite to that of the presently claimed inventive method of the appellants.

In the case of either the methods of the prior art described in Ritt or the inventive method of Ritt one skilled in the art would not have considered blowing

gas into the glass tube to create an overpressure. In the first case it would not make sense since the lower end is always closed and the overpressure could not be released through the lower end thereby avoiding deposition of alkali on the inner side of the glass tube. In the second case it is simply not possible to blow gas into the glass tube from the upper end because there is no opening. Therefore, the teachings of Ritt would lead one skilled in the art away from the presently claimed inventive method. The Examiner's allegation therefore seems to be based on hindsight.

With regard to the disclosures of Schul on page 14 of the Examiner's answer the Examiner's argument on page 14 that "the ends of the tubes of Schul are opened" is misleading. Actually, the ends of the tubes according to Schul are never closed so that they cannot be opened. Admittedly they are open.

The tube according to Schul is open at both ends, which results in a much higher gas flow and gas pressure in the glass tube in order to allow calibration of the glass tube. In contrast, according to the invention, it is only necessary to create an overpressure while the bottom of the glass tube is opened so that in that instance the alkali produced is directly transported out of the tube. Thereafter, according to the invention, there is no significant overpressure in the tube and there is also no need for an overpressure anymore.

Furthermore, Schul obviously does not teach the production of ampoules or vials or glass containers. The subject matter of this patent is to calibrate a silica glass tube initially having a thick wall and a big diameter, thereby producing

a silica tube having a thin wall and a smaller diameter. This is a well known and completely different process than that of Ritt and the present invention. The process of Schul is typically used when tubes are to be produced having a very precise outer diameter and wall thickness.

Additionally, the glass tube formed according to Schul is made of fused silica which is glass having a very high melting temperature containing only SiO_2 . For that reason the problem underlying the present invention, namely having alkali deposited on the interior of the glass tube cannot occur according to Schul (and, by the way, would not be prevented if the method of Ritt is employed). None of the steps of the methods of Schul that are used for the purposes of Schul would be employed in the method of Ritt.

For that reason, one skilled in the art would not have combined the disclosures of Schul with those of Ritt when being faced with the problem of making a glass container, such as an ampoules or a vial or the like, in which deposition of alkali on the interior of the glass container during its production is avoided. There is no logical reason to combine the disclosures of Schul with those of Ritt since entirely different articles are being made and different problems are being solved.

In addition, Schul does not explain how the overpressure is produced. When gas flows through an open tube of constant inner diameter as shown in the figures of Schull no overpressure is developed without more. Either a constriction is necessary in the tube or an opposing flow of gas into the tube at the other end

would be necessary to produce the overpressure. Schul does not show or teach the location of a constriction for producing the overpressure.

For the reasons presented in the appeal brief and the aforesaid additional reasons Honorable Board of Patent Appeals and Interferences is respectfully requested to overturn the rejection of claims 36 to 39 and 42 as unpatentable under 35 U.S.C. 103 (a) under 35 U.S.C. 103 (a) over Ritt, et al, in view of Bennett, et al, and Schul.

4. THE REJECTION OF CLAIMS 43 AND 44 AS OBVIOUS OVER RITT IN VIEW OF OTT

The Examiner's answer also briefly addresses the arguments to overturn the rejection of claims 43 and 44 as unpatentable under 35 U.S.C. 103 (a) over Ritt in view of Ott. These arguments were presented in second E of the argumentation section of the appellants' appeal brief.

Appellants have provided comparative experimental evidence on page 9 of their originally filed specification that shows that the alkali borate deposits on the interior surface of the glass tube and container made from it by their claimed method in which an overpressure is provided inside the glass tube during thermal processing as claimed in the amended claims is unexpectedly and surprisingly reduced by a factor of 2.

The appeal brief on pages 38 and 39 presents supporting arguments that explain that the aforesaid comparative experimental evidence should be

sufficient to overcome any alleged case of *prima facie* obviousness established by combining the disclosures of Ritt with Ott. Ott does disclose a glass having a composition that is similar to that of step a) of claim 43.

The answer on page 16 of the Examiner's answer is not sufficient to overcome this evidence.

Ritt only teaches that their method prevents impurities near the glass tube from entering the interior of the glass tube (see abstract, column 2, lines 8 to 10 and column 1, lines 53 to 59, of Ritt). Ritt does **not** teach or suggest that their method will suppress alkali borate evaporation and deposition on the inner surface of the glass tube due to high temperatures at the inner surface during thermal processing. Second the impurities disclosed in column 1, lines 53 to 59, include combustion gases and oil vapors as well as volatile glass components but do not necessarily include alkali borates because Ritt does not specifically disclose the problem of evaporation and deposition of alkali borates.

On the other hand, applicants' claims 43 and 44 are specifically limited to a method that suppresses evaporation and deposition of alkali borates in the interior of the glass tube and container made from it.

Furthermore merely because some impurities are prevented from reaching the inside of the tube from the outside environment during thermal processing does not mean that the sodium borate that is already present on the interior surface of the glass tube that is closed at both ends and is the starting point for the process of Ritt according to independent claims 1 and 6 of Ritt are removed by the process of Ritt or can be prevented from contaminating the inner surface

of Ritt. If they are already present on the interior surface of the glass tube of Ritt at the start of the process of Ritt, how could any feature of the process of Ritt prevent them from being deposited?

In addition, the generic teaching that "impurities" are prevented from entering the glass tube of Ritt does not make the prevention of sodium borate deposits on the inner surface of the glass tube obvious. The sodium borate, which may not be considered to be an impurity as defined or not defined by Ritt, evaporates from the inner surface of the glass tube when it is heated and is deposited on the inner surface. Ritt never describes the process of evaporation of alkali from the inner surfaces of the glass tube and does not describe any method of preventing the evaporation and deposition of the sodium borate.

In addition, the source of the impurity that appellants are preventing is the heated glass material of the glass tube, not the exterior environment. Thus the source of the impurity, namely the sodium borate, is already present in the interior of the glass tube because it is the glass material itself. Thus a method that prevents vapor from entering the glass tube would be ineffective in preventing the deposition of the heated tube.

Also Ritt does **not** provide any experimental evidence that their method operates successfully to prevent deposition of at least some impurities on the inner surface of the glass tube (It is highly unlikely that impurities are completely prevented from contaminating the inner surface of the tube by this method). In contrast, applicants provide convincing experimental evidence that sodium borate deposition is significantly and unexpectedly reduced by their method in

relation to a deposit that is found on a commercially made glass bottle by state of the art methods.

For the reasons presented in the appeal brief and the aforesaid additional reasons Honorable Board of Patent Appeals and Interferences is respectfully requested to overturn the rejection of claims 43 to 44 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al, in view of Ott, et al.

5. THE REJECTION OF CLAIMS 45 AND 46 AS OBVIOUS OVER RITT IN VIEW OF OTT AND FURTHER IN VIEW OF SCHUL

The Examiner's answer also briefly addresses the arguments to overturn the rejection of claims 45 and 46 as unpatentable under 35 U.S.C. 103 (a) over Ritt in view of Ott, and further in view of Schul. These arguments were presented in section F of the argumentation section of the appellants' appeal brief.

The same comments apply to claims 45 and 46 that were made in section 4 regarding claims 43 and 44.

For the reasons presented in the appeal brief and the aforesaid additional reasons Honorable Board of Patent Appeals and Interferences is respectfully requested to overturn the rejection of claims 45 to 46 are unpatentable under 35 U.S.C. 103 (a) over Ritt, et al, in view of Ott, et al, and Schul.

IV. SIGNATURE

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Michael J. Striker', with a long horizontal flourish extending to the right.

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